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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,455	02/21/2002	James C. Paulson	019957-011212US	3039

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EXAMINER	
RAO, MANJUNATH N	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,455	PAULSON ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *84-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *84-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER APPEAL BUT BEFORE A BOARD DECISION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2-17-06 has been entered.

New claims 84-92 are currently pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 84 and claims 85-92 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 84 is drawn to a method of sialylating a saccharide group on a recombinant glycoprotein, the method comprising contacting a saccharide group which comprises a galactose or an N-acetylgalactosamine acceptor moiety on a recombinant glycoprotein with a sialic acid donor moiety and a *Camplylobacter jejuni* α 2,3-sialyltransferase in a reaction mixture which provides reactants required for sialyltransferase activity for a "sufficient time and under appropriate conditions" to transfer sialic acid from said sialic acid donor moiety to said saccharide group. However, the metes and bounds of the phrase

"sufficient time and under appropriate conditions" are not clear to the Examiner. It is not clear to the Examiner as to what amount of time and what specific conditions are encompassed by the above phrase. A perusal of the specification did not provide the Examiner with a definition for the above phrase rendering the claim indefinite.

Claims 90 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 90 recites the phrase "less than 50 mUnits/mg of glycoprotein acceptor". It appears that by reciting 50 mUnits, applicants mean "50 milli Units" of the enzyme per milligram of glycoprotein acceptor. However, Examiner was unable to find such a specific definition for "mUnits". While generally it is understood that the letter "m" preceeding the word "Units" is "milli" (i.e., 1000^{th} of One Unit of the enzyme), it is not clear to the Examiner that applicants also mean the same. A perusal of the specification did not provide the Examiner with a specific definition of the abbreviation. Furthermore, it is also not clear as to how applicants define a Unit of the enzyme. Examiner was unable to find a specific definition for the "Unit" rendering the claim indefinite. Examiner requests clarification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 84-89, 92 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of sialylating a saccharide group on a recombinant

glycoprotein using the specific sialyltransferase (ST), α 2,3-ST isolated specifically from *C.jejuni*, at a concentration of at least 50 mUnits per mg of glycoprotein, wherein the concentration of glycoprotein is from about 1-10 mg/ml, does not reasonably provide enablement for such a method wherein any the concentration of the *C.jejuni* enzyme is less that 3 mUnits per mg of glycoprotein and wherein the concentration of the glycoprotein is more than 10 mg/ml. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 84-89, 92 are so broad as to encompass a method of sialylating a saccharide group on a recombinant glycoprotein using α 2,3-ST isolated specifically from *C.jejuni*, at a concentration less than 2 mUnits per mg of glycoprotein and wherein the concentration of the glycoprotein is more than 10 mg/ml. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the method of use of extremely small amounts of α2,3-ST enzymes and large amounts of glycoprotein broadly encompassed in the claimed method. Since the step of sialylation is quite complex and there is no clear documentation in the art that minute concentrations of the C.jejuni enzyme can be used to

successfully transfer sialic acid moiety to acceptors comprising large amounts of the acceptor glycopritens the method requires a knowledge of and guidance with regard to specific amounts of enzyme and the acceptor glycoprotein can be used in order to achieve sialylation. However, in this case the disclosure is limited to a method of sialylation using at least 50 mUnitsof the enzyme in a reaction comprising not more than 10 mg/ml of the glycoprotein. It would require undue experimentation of the skilled artisan to use any amounts less than 50 mUnits of α2,3-ST and more than 10 mg/ ml of the glycoprotein in the claimed method. The specification is limited to teaching the use of the α 2,3-ST from *C.jejuni* at a concentration of at least 50 mUnits per mg. of the glycoprotein and wherein the concentration of the glycoprotein does not exceed 10 mg/ml. but provides no guidance with regard to the method of using highly small amountsof the enzyme for sialylation. In view of the great breadth of the claim, amount of experimentation required to use the polypeptides in the claimed method, the lack of guidance, working examples, and unpredictability of the art in predicting function of small concentrations of the enzyme the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the method encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to perform enzyme assays as encompassed by the instant claims, the use of ultra small concentration of the enzyme such as α 2-3 ST to sialylate a glycoprotein with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable.

The specification does not support the broad scope of the claims which encompass the use of any or all concentration of bacterial α2,3-STs enzyme below 50 mUnits, because the

specification does not establish: (A) a rational and predictable scheme for using small concentration of the *C.jejuni* α2,3-ST polypeptide enzyme in the sialylating reaction; and (B) specific reaction conditions such as temperature of incubation, pH of the buffers or any other factor that would be amenable for use of such low concentration of the enzyme(C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a method of sialylation using very small amounts of C.jejuni α2,3-ST. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the amount of C.jejuni bacterial α2,3-ST for the claimed method is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the above rejection, applicants submit that the amended claims and the new claims overcome the previously held rejection. While that is so, the new claims have their own issues with enablement.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 84-92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 12, 19-20, 23, 28-29, 32, 45, 50-51, 59-61, 73, 80-81 of U.S. Patent No. 6,399,336. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 84-92 of the instant application and claims 1-3, 12, 19-20, 23, 28-29, 32, 45, 50-51, 59-61, 73, 80-81 of the reference patent are both directed to method of sialylating a glycoprotein using bacterial STs, specifically *C.jejuni* α 2,3-ST. The method of sialylation claimed in the instant application and in the reference patent a good number of limitations are identical to one another. The portion of the specification (and the claims) in the reference patent that supports the recited method includes several embodiments that would anticipate the method claimed in claims 83-92 herein. Claims 84-92 of the instant application listed above cannot be considered patentably distinct over claims 1-3, 12, 19-20, 23, 28-29, 32, 45, 50-51, 59-61, 73, 80-81 of the reference patent when

there is specifically recited embodiment that would anticipate mainly claims 84-92 of the instant application. Alternatively, claims 84-92 cannot be considered patentably distinct over claims 1-3, 12, 19-20, 23, 28-29, 32, 45, 50-51, 59-61, 73, 80-81 of the reference patent when there is specifically disclosed embodiment in the reference patent that supports claims 1-3, 12, 19-20, 23, 28-29, 32, 45, 50-51, 59-61, 73, 80-81 of that patent and falls within the scope of claims 84-92 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1-3, 12, 19-20, 23, 28-29, 32, 45, 50-51, 59-61, 73, 80-81 of the reference by selecting a specifically disclosed embodiment that supports those claims. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1-3, 12, 19-20, 23, 28-29, 32, 45, 50-51, 59-61, 73, 80-81 of the reference patent.

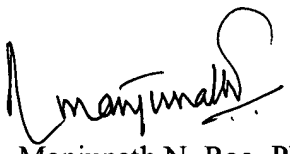
In response to the above rejection, applicants have indicated that they will file a T.D once outstanding rejections are resolved. However, Examiner maintains the rejection for reasons of record until such time that a T.D. is filed.

Conclusion

None of the claim is allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization

where this application or proceeding is assigned is 703-872-9306/9307 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

April 25, 2006